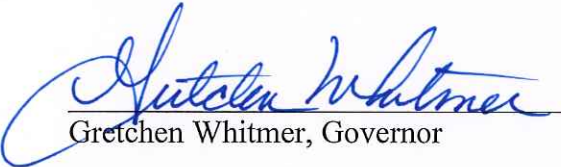


DEPARTMENT OF HEALTH AND HUMAN SERVICES
BUREAU OF EPIDEMIOLOGY AND POPULATION HEALTH
REPORTING OF POISONINGS DUE TO THE USE OF PRESCRIPTION OR ILLICIT
DRUGS
EMERGENCY RULES

CERTIFICATE OF NEED FOR EXTENSION OF EMERGENCY

Pursuant to Section 48(1) of 1969 PA 306, as amended, MCL 24.248(1), I hereby certify that it is necessary to extend the effectiveness of the Bureau of Epidemiology and Population Health Reporting of Poisonings Due to the Use of Prescription or Illicit Drugs Emergency Rules, which were filed with the Secretary of State on October 26, 2018, for an additional 6 months. Therefore, the Reporting of Poisonings Due to the Use of Prescription or Illicit Drugs Emergency Rules shall remain effective until October 28, 2019.


Gretchen Whitmer, Governor

4/16/19
Date

DEPARTMENT OF HEALTH AND HUMAN SERVICES
BUREAU OF EPIDEMIOLOGY AND POPULATION HEALTH
DIVISION OF ENVIRONMENTAL HEALTH
REPORTING OF POISONINGS DUE TO THE USE OF PRESCRIPTION OR ILLICIT
DRUGS
EMERGENCY RULES

Filed with the Secretary of State on October 26, 2018

These rules take effect upon filing with the Secretary of State and shall remain in effect for 6 months.

By authority conferred on the department of health and human services by section 8 of 1978 PA 312; sections 2221, 2226, 2233, 5111 of 1978 PA 368; Executive Reorganization Order No. 2015-1; and section 48 of 1969 PA 306, being MCL 325.78, MCL 333.2221, MCL 333.2226, MCL 333.2233, MCL 333.5111, MCL 400.227, and MCL 24.248.

FINDING OF EMERGENCY

These emergency rules are promulgated by the Department of Health and Human Services to address the significant increase in both fatal and nonfatal prescription and illicit drug overdoses in this state. There is no current requirement for health professionals or health facilities to report data from overdoses and/or death from prescription and illicit “street” drugs. Requiring health professionals and health facilities to report specific data will identify the drugs associated with overdoses and/or deaths and ensure a proportionate share of critical resources and funding is made available to all areas of the state based upon findings from the reporting data. Further, the identification of specific drug(s) causing deaths will improve the accuracy of death certificates issued by the state when many cite only “unspecified” or “drug abuse” on the death certificate.

Opioids—prescription and illicit—are currently the main driver of drug overdose deaths. Twenty-six states, including Michigan, had statistically significant increases in drug overdose death rates between 2015 and 2016. [Hedegaard H, Warner M, Miniño AM. *Drug overdose deaths in the United States, 1999–2016*. NCHS Data Brief, no 294. Hyattsville, MD, National Center for Health Statistics; 2016.] The current numbers for the first quarter of 2018 are disturbing. On July 17, 2018, Sparrow Forensic Pathology Services, a division of Sparrow Hospital, released its first quarter numbers of drug-related deaths in five Michigan counties: Eaton, Ingham, Ionia, Isabella, and Shiawassee. Summarily, total drug-related deaths have increased 20% compared to the same time period in 2017. Further, opioid-related deaths are up 17.9% from the same time last year. The synthetic “street” drug, Fentanyl, was responsible for 7

October 24, 2018

more deaths in the state from last year, which is a 70% increase in that measure. Deaths from methadone, cocaine, and amphetamine/methamphetamine also increased. [Sparrow -Office of the Medical Examiner -2017 Annual Report,

[http://www.sparrow.org/upload/docs/2017%20Annual%20Report%20\(1\).pdf](http://www.sparrow.org/upload/docs/2017%20Annual%20Report%20(1).pdf).]

The data provided by Sparrow is limited to only five counties in Michigan. The issue then becomes what the impact of prescription and illicit drugs is statewide. Other data statistics suggest that there are undercounts of deaths related to prescription opioids, because it does not include deaths that are associated with pharmaceutical fentanyl, tramadol, and other synthetic opioids that are used as pain relievers. [Centers for Disease Control and Prevention, Opioid Data Analysis, 2017 <https://www.cdc.gov/drugoverdose/data/analysis.html>.]

Prescription opioids continue to be involved in more overdose deaths than any other drug, and all the numbers are likely to underestimate the true burden, given the number of overdose deaths where the type of drug is not listed on the death certificate [Hedegaard, *Drug overdose deaths in the United States, 1999–2016*. NCHS Data Brief, no 294. Hyattsville, MD: National Center for Health Statistics. 2017]. The state has been working to increase the availability of information about drugs related to overdose deaths by providing more resources for drug testing. In 1999, 47% of the state's overdose deaths were listed as being caused by an unspecified drug. By 2016, 13.2% of the state's overdose deaths were listed as involving an unspecified drug. [Dr. Eden Wells, Chief Medical Executive for the Michigan Department of Health and Human Services, as quoted in the *Detroit Free Press*, June 29, 2018.] While the numbers show an improvement in specification, the increase in overdoses leading to death clearly demonstrate that more resources are needed.

Currently, there is no requirement for health professionals and health facilities to report poisonings from prescription and/or illicit drugs, making it difficult for the department to respond to overdoses, identify new drugs causing morbidity, and preventing future overdose events. With the increase in the popularity and continual addition of new synthetic opioid “street” drugs and associated increase in overdoses and associated deaths, the Department needs to collect the data from health professionals and health facilities quickly to assess critical needs of counties and their population and provide appropriate health warnings, rehabilitation, and preventative care for Michigan citizens. As the impact of the opioid crisis evolves, the Department of Health and Human Services needs to understand the use of other drugs in the population.

The Department of Health and Human Services therefore finds that the reason for emergency requires the promulgation of emergency rules without following the notice and participation procedures required by sections 41, 42, and 48 of 1969 PA 306, MCL 24.241, MCL 24.242, and MCL 24.248 of the Michigan Compiled Laws.

Rule 1. (1) As used in these rules:

- (a) "Department" means the department of health and human services.
- (b) "Drug" means any of the following as provided in 1978 PA 368, MCL 333.17703:
 - (i) A substance recognized or for which the standards or specifications are prescribed in the official compendium.
 - (ii) A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.
 - (iii) A substance, other than food, intended to affect the structure or a function of the body of human beings or other animals.
 - (iv) A substance intended for use as a component of a substance specified in subdivision (i), (ii), or (iii), but not including a device or its components, parts, or accessories.
- (c) "Health facility" means any facility or agency licensed under article 17 of the public health code, MCL 333.20101 to 333.22260 that provides health care services. "Health facility" includes a hospital, clinical laboratory, surgical outpatient facility, health maintenance organization, nursing home, home for the aged, county medical care facility, and ambulance operation. Health Facility does not include any facility or agency that is prohibited by law under 42 CFR Part 2 from releasing records on substance abuse disorders.
- (d) "Health professional" means a person licensed under article 15 of the public health code, MCL 333.16101 to 333.18838, in medicine, osteopathic medicine, as a physician's assistant, or nurse practitioner.
- (e) "Illicit drugs" means any Schedule 1 drug, new and emerging psychoactive substances, or Schedule 2-5 drugs that are not obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of the practitioner's professional practice.
- (f) "Local health department" means a public health department established under the provisions of article 24 of the public health code, MCL 333.2401 to 333.2498, to protect the public health and prevent disease within a specific geographic area.
- (g) "Poison" means a substance which, when ingested, inhaled or absorbed, injected into, or developed within the body, causes damage to structure or disturbance of function in the body.
- (h) "Poisoning" means a morbid condition, including death, produced by a poison.
- (i) "Public health investigation" means the collection of medical, epidemiologic, exposure, and other information to determine the magnitude and cause of illness or injury, which is used to determine appropriate actions to prevent or mitigate additional illness or injury.
- (j) "Substance use disorder services" means substance use disorder prevention, treatment, and rehabilitation services established under the provisions of article 6 of the public health code, MCL 333.6230 to 333.6251, to reduce the consequences of substance use disorders in individuals and communities.

Rule 2. (1) Health professionals and health facilities shall provide reports when requested by the department or local health department. The department or local health department shall notify

health professionals and health facilities when reports of prescription or illicit drug poisonings shall be submitted. Both of the following apply:

(i) Reports shall be made within 5 working days following request by the department or local health department.

(ii) Reports shall be provided to the department and/or local health department that makes the request.

(2) Reports may be provided by health professionals and health facilities, without departmental or local health department request, when the reporting entity believes that public health investigation is needed to protect the public.

(3) Nothing in this rule shall be construed to relieve a health professional or health facility from reporting to any other entity as required by state, federal, or local statutes or regulations or in accordance with accepted standard of practice, except that reporting in compliance with this rule satisfies the reporting requirements of 1978 PA 368, MCL 333.1101 *et seq.*

(4) The department shall develop procedures and systems to enable electronic laboratory and case reporting by health care providers and facilities to reduce reporting burden and ensure efficiency and security of information sharing.

Rule 3. (1) Reportable information is information specifically related to patients with known or suspected poisonings due to use of prescription or illicit drugs, including fatal and nonfatal overdoses.

(2) International Classification of Disease Codes (ICD) for medicinal and illicit drug poisonings and toxicological laboratory evidence shall be considered evidence of poisoning.

(3) The health professional or health facility shall submit its report in a format that ensures the inclusion of the information listed under subdivisions (a) to (e) of this subrule as applicable.

(a) All of the following information with respect to the patient shall be provided:

(i) Last and first name and middle initial.

(ii) Sex.

(iii) Race, if available.

(iv) Ethnic group, if available.

(v) Birth date or age.

(vi) Residential address.

(vii) Telephone number.

(viii) If the individual is a minor, the name of a parent or guardian.

(b) If the reporting entity is a health care provider or health facility other than a clinical laboratory, the following diagnostic information shall be provided, in addition to information specified in subrule (3)(a) of this rule:

(i) The date of diagnosis.

(ii) The diagnosis, including ICD diagnostic code, if available.

(iii) Brief narrative of the poisoning event, including date, location, and type of medicine or drug involved, and any other information considered by the health professional/health facility to be related to health of the public.

(iv) Brief narrative of the patient's signs and symptoms, clinical findings, results of diagnostic tests, and clinical outcome.

(c) If the reporting entity is a clinical laboratory, the following information shall be provided in addition to information specified in subrule (3)(a) of this rule:

(i) Unique specimen ID and/or accession number.

(ii) Name of the clinical test performed.

(iii) Test result, including units of measurement, including LOINC and SNOMED codes.

(iv) Laboratory reference range including units of measurement.

(v) Date the laboratory test was ordered.

(d) Name, address, telephone, and other contact information shall be provided for the reporting health professional. If the reporting entity is a health facility, contact information for the diagnosing/treating/ordering physician shall be provided.

(e) Name, address, telephone and other contact information for the health facility shall be provided if the reporting entity is the facility.

Rule 4. (1) The department or local public health department, upon receiving a report under subrule (2), may investigate to determine the accuracy of the report, a patient's source of drug, and adverse health effects resulting from the poisoning due to drugs.

(2) The department and local public health departments shall collaborate in the development of procedures for processing reports of poisonings and conducting follow-up investigations to ensure efficient, non-duplicative, and effective public health response.

(3) Requests by the department or local public health departments for individual medical and epidemiologic information to validate the completeness and accuracy of reporting are specifically authorized.

(4) Information from reported cases shall be kept in a secure manner when not in use. Information stored electronically shall be maintained in a secure manner, accessible only by department or local health department program staff through password protected user accounts.

(5) Except as provided in subrule (6) of this rule, the department and local health departments shall maintain the confidentiality of all reports and other information received under these rules and shall not release reports or information that may be used to directly link the information to a particular individual.

(6) The department and local health departments may release reports or information, otherwise protected under subrule (5) of this rule, under any of the following conditions:

(a) If the department has received written consent from the individual, or from the individual's parent or legal guardian, requesting the release of information.

(b) As necessary for the department to carry out its duties under 1978 PA 368, MCL 333.1101 to 333.25211.

(c) If necessary for the purpose of public health activities designed to prevent poisonings due to use of prescription or illicit drugs.

(d) If necessary for the purpose of research designed to develop or contribute to generalizable knowledge, with documented approval by the department's institutional review board.

(e) If the director of the department determines that release of information is crucial to protect the public health against an imminent threat or danger.

(7) Nothing in this rule shall be construed to relieve or preempt any other entities from investigating hazards associated with drug poisonings under state, federal, or local statutes or regulations.

(8) Reports submitted to the department or local health department under Rule 3 are not public records and are exempt from disclosure pursuant to the freedom of information act, 1976 PA 442, MCL 15.231 *et seq.*

(9) Reports and information submitted to the legislature by the department as necessary to carry out its duties shall not contain any identifiable information. Aggregate information concerning public health that is released to the public shall not contain information that allows individuals to be identified.

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nancy Vreibel
Senior Chief Deputy Director

Date:

Pursuant to Section 48(1) of 1969 PA 306, MCL 24.248(1), I hereby concur in the finding of the Department of Health and Human Services that circumstances creating an emergency have occurred and the public interest requires the promulgation of the above rules.

Brian Calley
Acting Governor

Date: